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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,155	12/27/2004	Imao Mikoshiba	Q85258	5395

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,155	MIKOSHIBA ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 9, 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-13 and 17-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-13 and 17-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/14/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Amendment filed January 9, 2008 has been received and entered into present application. Claims 1-10, and 14-16 were canceled and claims 17-25 were added by applicant. Thus claims 11-13 and 17-25 are pending.

Applicants' arguments, filed January 9, 2008 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 (new grounds of rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-13, 17-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has claimed a method of preventing arteriosclerotic disease, however applicant has not shown how one of skill in the art could use the invention as claimed.

Arteriosclerosis is a complicated disease, with many different risk factors and often results as a complication from other disorders. To prevent arteriosclerotic disease, applicant's invention would have to stop all people from developing the disease, and applicant has not even shown the ability to treat or reduce arteriosclerotic disease.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The quantity of experimentation necessary to develop a method of preventing arteriosclerosis is large (1) given the complete lack of direction provided (2) and the absence of any working examples directed to arteriosclerosis or any heart related diseases (3). The nature of the invention is prevention of a complicated disease in humans with type II diabetes (4) which is a unpredictable art (7) despite the relative skill of those in the art being high (6) the state of the prior art is such that prevention of arteriosclerosis is something which has not been achieved and a great deal of direction and testing would be necessary for one of skill in the art to use such a method (5). The breadth of the claims is large due to prevention of a disease such as arteriosclerosis (8).

Claim Rejections - 35 USC § 103 (new grounds of rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-13, and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohnota et al. (Novel Rapid- and Short-Acting Hypoglycemic Agent...) (already of record, the reasons set forth at pages 6-10 of previous office action dated July 13, 2007, of which reasons are herein incorporated by reference) in view of Larner et al. (US 5,428,066).

New grounds of rejection necessitated by amendment to claims adding asteriosclerotic disease and addition of claims 17-25.

Claim 11 claims a method of preventing or inhibiting arteriosclerotic disease, comprising administering to a type II diabetic patient, 5-45mg of mitiglinide or a pharmaceutically acceptable salt. Claims 12 and 13 further limit the dosage to 5-22mg (claim 12) and 10-11mg (claim 13).

Ohnota et al. teaches a method of treating type II diabetic patients with KAD-1229/mitiglinide calcium hydrate (page 494, column 2, paragraph 3). The only dosages used/taught in Ohnota et al. were during the trials on rats and doges which were 0.3-3.0mg/kg. This dosage range, as discussed in the previous office action, would translate to 16-65mg for a 120lb person, or in the case of the 10kg dogs used in Ohnota et al. (page 490, paragraph 5) dosage ranges of 3-30mg. Applicant claims a "patient" but does not specify that it cannot be a rat or dog (such as those tested in Ohnota et al.). Since dogs get diabetes, it is a reasonable interpretation of "patient". Furthermore, Ohnota et al. teaches treatment of humans with KAD-1229 and although specific dosages were not tested on humans, the dosage ranges are often the same, dependent on body weight. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention that Ohnota et al. teaches dosages that overlap the range of claims 11-13, and although they may not be directed to human patients, it would be within the range of normal experimentation and optimization for one of ordinary skill in the art.

Applicant's attention is drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is

the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Although the present claims are drawn to mg/day dosage amounts, such a motivation is nonetheless relevant.

Ohnota et al. teach treatment of type II diabetes with mitiglinide calcium hydrate but does not teach treating or preventing arteriosclerotic disease. However, Ohnota et al. does teach that their method would reduce diabetic complications (page 490, paragraph 1). Larner et al. teach that it is widely known that non-insulin dependent diabetes mellitus (NIDDM) is frequently associated with arteriosclerosis ad other coronary artery diseases (column 1, lines 55-60). Furthermore, NIDDM is a known risk factor for coronary artery disease (column 1, lines 60-65) and thus it would have been obvious to one of ordinary skill in the art at the time of the invention that treatment of type II diabetes would also treat/inhibit progression of diabetic complications, and specifically arteriosclerosis. Thus claims 11-13 are unpatentable over Ohnota et al. in view of Larner et al.

Applicant argued that the instant application involves more than merely lowering blood glucose levels as taught by Ohnota et al. however, the method of Ohnota et al. is the same as the method claimed, and one of ordinary skill in the art at the time of the invention would have known that by administering the same drug as the same/similar dosages to a type II diabetic patient would accomplish the same things and since applicant has failed to show unexpected results there is no reason to believe the

method of Ohnota et al. would not result in the same effects as that claimed by the instant application.

In claim 17, applicant claims the type II diabetic patient treated in claim 11 is a patient who's HbA_{1c} values is not less than 6.5% and the 1-2 hour value of the postprandial plasma glucose is not less than 200 mg/dL even after more than 8-week therapy. Applicant has added a very specific patient, however that patient is still a type II diabetic patient who would benefit from the treatment of claim 11 and Ohnota et al., and although Ohnota et al. does not disclose such specifics, it would be obvious to one of skill in the art at the time of the invention that a patient with those levels would also be in need of lowering postprandial blood glucose levels and thus the method of Ohnota et al. would be expected to help the patient of claim 17, and claim 17 is unpatentable over Ohnota et al.

Claims 18-25 claim the method of claims 11-13, and 17 in which the mitiglinide is administered 5 or 10 minutes before the start of a meal. Ohnota et al. does not teach administering their composition at any particular time, however administering glucose regulating drugs to diabetics before 0-15 minutes before meals is common and well known in the art. Furthermore, Ohnota et al. teaches that the peak levels of their composition were reached at 30 mins, and thus it would be obvious to one of ordinary skill in the art at the time of the invention that administration just prior to the meal would lead to desirable effects of a peak mitiglinide level occurring at the time in which glucose levels start to spike. Thus claims 18-25 are unpatentable over Ohnota et al.

Conclusion

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 8:30am-6pm Mon-Thu, 8:30am-5pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614